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Jean-Jacques Caboche

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EXAMINER

OLSON, ERIC

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Detailed Action

This office action is in response to Applicant's submission filed February 10, 2009 After Final.

3. Applicant's amendment, submitted February 10, 2009, will not be entered as it introduces new issues for search and consideration. Specifically the base claims 19, 31, and 38 have been amended to require that the branched glucose polymers have a certain specific distribution of branching side chains. Therefore the amendment will not be entered.

5. Applicant's terminal disclaimer, submitted February 10, 2009, disclaiming the terminal portion of any patent granted on this application extending beyond the expiration of US patent 7015318, has been accepted and entered into the record. This disclaimer is persuasive to overcome the rejection of instant claims 19-22 under the doctrine of obviousness-type double patenting for claiming the same invention as claims 1-4 of 7015318. Therefore the rejection is withdrawn.

11. Applicant's arguments, submitted February 10, 2009, with respect to the rejections of record in the previous office action, have been fully considered and not found to be persuasive for reasons of record in the previous office action and as discussed below:

First, with respect to the rejection under 35 USC 112, Applicant argues that the claims are not directed to novel branching enzymes and that methods of obtaining and purifying these branching enzymes are not recited in the claims. However, in order to actually practice the full range of the claimed invention, one skilled in the art must be able to obtain the required technical means without undue experimentation. Because the scope of the claims includes all branching enzymes, the claims must be enabled for all said enzymes.

According to MPEP 2164.03, The “amount of guidance or direction” refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. >See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004) Also, “in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. In *re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In *re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity).

Art Unit: 1623

See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work.”

Biological enzymes are less predictable than, for example, chemical reagents or mechanical tools. They are made by nature rather than by man, and operate according to principles that have not been fully characterized. Coming up with a particular enzyme for a particular purpose is difficult and cannot be done routinely in the same fashion as one would go about constructing a mechanical apparatus for a particular purpose.

Therefore the suitability of the full genus of branching enzymes for the claimed purpose as well as the ability of one skilled in the art to obtain these enzymes would be in doubt.

While Applicant asserts that the invention is directed only to a method of making branched glucose polymers that happens to utilize a variety of branching enzymes, the ability to make and use the full range of branching enzymes is an essential part of the invention, and given the wide scope of enzymes included within the claim language, and the unpredictability of both the availability and functionality of biological enzymes, this would constitute an undue experimental burden.

In response to Applicant's request for assistance, amending the claims to limit the branching enzyme to one or more enzymes that are supported in the specification as originally filed would overcome this rejection. However, please note that any amendment introducing new issues for search and consideration after a final rejection will not be entered without a request for continued examination.

As regards the rejections made under 35 USC 103, Applicant argues that claims 19-22 are nonobvious over Okada in view of Senkeleski because Senkeleski includes a hydrolysis step that is incompatible with the claimed invention. However, Senkeleski is relied upon not for the teaching of enzymatic hydrolysis, but only for its teaching of high-pressure steam cooking gelatinization. The two steps, gelatinization and enzymatic hydrolysis, are separate steps that can be carried out separately for different purposes. Just as the enzymatic hydrolysis step could be performed on any gelatinized starch, the gelatinization step could be used under any circumstances where a gelatinized starch is required. One of ordinary skill in the art would recognize the high temperature gelatinization step used by Senkeleski as being a separate step that could be performed independently in any circumstance where gelatinized starch was required. One of ordinary skill in the art would also have realized that the enzymatic reactions disclosed by Okada could be carried out on starch gelatinized by this method, and that the two steps could be combined without the hydrolysis step, for example if a more rapid gelatinization step is needed. Therefore the rejection is seen to be proper and maintained.

Furthermore, with regard to the rejection of claims 31-37 as obvious over Okada in view of Senkeleski in view of Sandstrom, all arguments made above apply. Furthermore, Applicant argues that Sandstrom teaches only polymers having beta-glycosidic linkages, and that modifying these polymers to not have beta-glycosidic linkages amounts to a posteriori reasoning. However, as described in the previous rejection, the only reason that the beta-glycosidic linkages are present at all in the

Art Unit: 1623

polymers of Sandstrom et al. is because of the particular method by which they were treated to increase the branching degree. Therefore, the property of having beta-glycosidic linkages is essentially equivalent to the property of having been made by the chemical method described by Sandstrom et al., while the property of having no beta-glycosidic linkages is essentially equivalent to the property of having been made by enzymatic methods. As described in the previous rejection, it would have been obvious to make branched polymers having the branching, retrogradation, molecular weight, and reducing sugar properties recited in claims 31-37 by enzymatic instead of chemical methods. Therefore these enzymatically-synthesized polymers would be identical to those claimed.

For these reasons, these previously applied rejections are all deemed to be proper and maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

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/Eric S Olson/
Examiner, Art Unit 1623
2/18/2009

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623